

Applicant : Nai-Kong CHEUNG
U.S. Serial No.: 10/621,027
Filed : July 16, 2003
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REMARKS

By this Amendment, claims 120-148 have been canceled without prejudice, and new claims 149-188 have been added.

Support for the new claims can be found in the originally filed claims and in the canceled claims. Accordingly, there is no issue of new matters. Applicant respectfully requests the Examiner to enter the new claims. Upon entry, claims 149-188 will be pending and under examination.

1. Rejection under 35 U.S.C. § 102(b)

The Examiner states:

Claims 67, 80, and 82-85, which are rejection under 102(b) by Jamas et al. The statement in independent claim 67, "capable of enhancing efficacy of an antibody," and subsequent clarification of the antibody to be "foreign to the immune system of the host;" these limitations are given no patentable weight... See page 3 of the July 13, 2005 Final Office Action.

In response, but without conceding the correctness of the Examiner's position and to expedite the prosecution of this Application, Applicant has canceled claims 67, 80 and 82-85 without prejudice. New claims do not contain the above-mentioned issues, thereby rendering this ground of rejection moot.

The Examiner further states:

[T]he only component of the composition is the glucan. An antibody is not explicitly part of the composition... Therefore, the glucan is taught by Jamas et al. See page 3 of the July 13, 2005 Final Office Action.

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Applicant respectfully maintains that the claims that were presented in the originally filed application, and also, the new claims that were subsequently presented or are currently pending *ALL* explicitly recite "a glucan" and "an antibody". It has been shown that Applicant's claimed composition synergistically enhances the efficacy of antibodies that, for example, target cancer or tumor cells (e.g., see page 7, lines 5-21, of the specification). The claimed antibody-enhancing composition is neither disclosed nor taught by Jamas et al., as alleged by the Examiner. In addition, the glucan and antibody component can be administered simultaneously or sequentially. See, for example, page 24 of the specification. In this example, the antibody was administered intravenously twice weekly and the glucan was administered orally daily. The results show that the claimed composition suppresses tumor growth. See page 24, line 35, to page 25, lines 1-3, of the specification.

2. Rejection under 35 U.S.C. § 103(a)

The Examiner states:

Claims 68-79, and 83, which are rejected under 103(a) by Jamas et al., Dorothee Herlyn, Yan et al., Dante J. Marciani, Cheever et al., Chu et al., and Lane et al. has been maintained. These claims are maintained for the same reason as the 102(b) rejection outlined above. The amendments to the claims inserting statements of intended use for the glucan are given no patentable weight. See page 3 of the July 13, 2005 Final Office Action.

In response, Applicant respectfully maintains that Jamas et al., Dorothee Herlyn, Yan et al., Dante J. Marciani, Cheever et al., Chu et al., and Lane et al. do not disclose, teach, or motivate a person of ordinary skill in the art to make or use the claimed

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composition. Applicant has discovered that, when glucan is orally administered with the antibody, the anti-tumor effect of the antibody is enhanced synergistically (as compared to administering the antibody alone). See, for example, page 7, lines 19-21, of the specification (stating that glucan alone and mAb 3F8 alone "showed no anti-tumor effect," and glucan and mAb 3F8 showed "highly significant tumor shrinkage and suppression.").

The Examiner further states:

Additionally, the statement further defining the glucan to have mixed linkages can be reasonably interpreted to include branched glucan as taught by the prior art references cited on the record. See page 3 of the July 13, 2005 Final Office Action.

Claims 81 and 88 are rejected under 35 U.S.C. 103(a) by Jamas et al. Dorothee Herlyn, Yan et al., Dante J. Marciani, Cheever et al., Chu et al., and Lane et al.... Claims 81 and 88 contain the same problem as the independent claim from which it depends; namely the language "mixed linkages" can reasonably be interpreted to include 1,3 beta backbone glucans with branches, which is taught by the prior art of record. See page 5 of the July 13, 2005 Final Office Action.

In response, but without conceding the correctness of the Examiner's position and to expedite the prosecution of this Application, Applicant has canceled claims 67-79, 81, 83 and 88 without prejudice. New claims do not contain the above-mentioned issues, thereby rendering this ground of rejection moot.

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3. Rejection under 35 U.S.C. § 112

The Examiner states:

Claims 67, 81, and 88 are rejected under 35 U.S.C. § 112, second paragraph ... [because] [t]he limitation of "mixed linkages" found in these claims is indefinite and ambiguous. These limitations can be reasonably interpreted to mean a 1,3 beta backbone with either branched chains coming [from] the backbone itself, or mixed linkages within the backbone itself.

Claims 86 and 87 are rejected under 35 U.S.C. § 112, second paragraph, because claims that depend from an indefinite claim are also indefinite if they fail to obviate the reason the claim(s) from which they depend are rejected. See page 5 of the July 13, 2005 Final Office Action.

In response, but without conceding the correctness of the Examiner's position and to expedite the prosecution of this Application, Applicant has canceled claims 67-79, 81, 83 and 88 without prejudice. New claims do not contain the above-mentioned issues, thereby rendering this ground of rejection moot.

4. Withdrawal of claims directed to a non-elected invention

The Examiner states:

Newly submitted claims 89-119 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly presented claims contain glucan and an antibody, wherein the antibody governs the classification of the invention, classified in class 436/547.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by originally presentation for prosecution on the merits.

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Accordingly, claims 89-119 [are] withdrawn from consideration as being directed to a [sic] non-elected invention. See 37 CFR § 1.142(b) and MPEP § 821.03. See page 4 of the July 13, 2005 Final Office Action.

In response, Applicant respectfully maintains that the claims presented in the originally filed application and the claims examined on the merits by the Examiner *explicitly recite both glucan and antibody*. For example, see claim 67 in the May 25, 2004 Preliminary Amendment. According to MPEP § 2111, pending claims must be given their broadest reasonable interpretation *consistent with the specification*, and the words in the claims must be given their plain meaning. Claims 67 as well as claims that depend on claim 67 do not limit the composition to only a single component, and the specification does not support the limitation imported into the claims by the Examiner.

Applicant maintains that it is not necessary to physically combine the glucan and the antibody prior to administration. For instance, Applicant has discovered that a composition with enhanced anti-tumor activity can be produced in vivo by administering the antibody intravenously and the glucan orally, and that the combination of glucan and antibody has a synergistic effect (as compared to administering either the glucan or antibody alone). See page 7, lines 5-21, of the specification.

Therefore, claims 89-119 or other similarly worded pending claims, such as claims 168-188, are not directed to a non-elected invention because the claims that were examined on the merits *do not contain the limitation(s) introduced or as construed by the Examiner*. If, however, it is the Examiner's position that the claims that were examined on the merits are directed to two or more distinct and independent inventions, Applicant respectfully

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requests the Examiner to issue a restriction requirement prior to the examination of the pending claims.

CONCLUSION

Applicant respectfully requests the Examiner to reconsider and withdraw the rejections in the Final Office action and to place this Application in conditions for allowance.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee other than the TWO HUNDRED AND TWENTY-FIVE DOLLARS (\$225.00) fee for two-month extension of time and the THREE HUNDRED AND NINETY-FIVE DOLLARS (\$395.00) fee for the Request for Continued Examination is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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